

PRECLINICALTRIALS.EU

Section 1. General information

1. * Title of the study

Enter the full title of the study

2. Acronym/short title

Enter optional acronym/short title for the study

3. * Contact details

Give the name of the main administrative contact for the study

Name

Role

What is the role the main contact in the study (e.g. executive researcher, research group supervisor)?

Email address

Provide the email address of the main contact

4. * Study centre details

Give the details of the institutions where the experiments will be undertaken. Add additional lines if there is more than one

None selected



5. * Sources of support

Give the sources of financial support for the study

- Industry
- Investigator driven
- Grants
- Other

6. * Start date

The date the study started or is expected to start

7. * Expected end date

The date the study ended or is expected to end

8. * Study status

Please indicate what the current status of the study is

- Not started
- Active
- Completed but not published
- Completed and published (abstract)
- Completed and published (full-text)
- Study interrupted

Section 2. Study design**9. * Field of medicine**

To what field of medicine does this study relate? (e.g. cardiology, oncology, neuroscience)

10. * Health condition/problem studied

Give the health condition or problem the study investigates

11. * Intervention type

What type of intervention is being tested in the study?

- Compound
- Delivery method
- Retention
- Model optimisation
- Surgery
- Other

12. * Study stage

Please indicate the stage of the study

- Stage 1 - Fundamental information to understand biology
Investigate the understanding of biology to discover and develop new therapeutic products (e.g. in vitro studies, genetic studies)
- Stage 2 – Exploratory study
Hypothesis-generating research. Normally pilot studies are stage 2 studies.
- Stage 3 – Confirmatory study
Final study confirming (or rejecting) a single hypothesis, these are normally blinded, randomized, controlled trials

13. * Hypotheses

Formulate the hypotheses for this study. This field is mandatory if Study Stage is Stage 3 but otherwise not.

14. * Primary endpoint(s)

What is the primary endpoint of the study? Please clarify what will be measured, how this will be measured and at what timepoint (e.g. efficacy based on Left Ventricular Ejection Fraction after 4 weeks).

- Safety
- Feasibility
- Efficacy

15. Secondary endpoint

What is the secondary endpoint of the study?

16. * Are animals exclusively used for this research question?

Please indicate if the animals (or tissues) are used for this study only

- Yes
- No

17. * Species

Select the appropriate species for the study

- | | | | |
|-------------------------------------|----------------------------------|---------------------------------|--------------------------------|
| <input type="checkbox"/> Cat | <input type="checkbox"/> Dog | <input type="checkbox"/> Ferret | <input type="checkbox"/> Goat |
| <input type="checkbox"/> Guinea pig | <input type="checkbox"/> Hamster | <input type="checkbox"/> Horse | <input type="checkbox"/> Mouse |
| <input type="checkbox"/> Monkey | <input type="checkbox"/> Pig | <input type="checkbox"/> Rabbit | <input type="checkbox"/> Rat |
| <input type="checkbox"/> Sheep | <input type="checkbox"/> Other | | |

18. Strain

Provide the strain or other specifications on the species

19. * Sex

Indicate the sex of the animals in the study

- Male
- Female
- Both

20. * Animal model used

What animal model was used for the study

21. * Sample size calculation

Please indicate if a sample size calculation was performed in advance and if so, please specify the sample size calculation. This usually includes alpha, beta, minimal detectable difference and expected number of drop-outs (due to mortality or other causes).

- No
- Yes

22. * Sum of animals in study arms

Indicate the total number of animals which are expected to be analysed in total (exclude expected procedural drop-out)

23. * Groups

Please indicate all of the study groups/arms and their purpose



24. * Randomisation

Give details about the study randomisation

Are the animals randomly allocated to the experimental groups?

- No - please explain why randomisation was not performed
- Yes

25. * Blinding

Are the investigators involved in the experiment blinded to the allocation of the animals to the experimental groups?

Are the investigators blinded?

- No
- Yes
- Yes partially, because

Is the assessment of outcome(s) blinded?

- No
- Yes
- Yes partially, because

26. * Placebo-controlled

Was one of the arms of the study a placebo arm?

- Yes
- No

27. * Was a pilot experiment performed?

Did you perform a pilot experiment before planning the current experiment?

- Yes
- No

28. * Follow-up duration

How long will the follow-up be?

29. Tissue sharing

If animal tissue sharing is possible please indicate what tissues you are able to share

- | | | | |
|--|---------------------------------|---------------------------------|--------------------------------------|
| <input type="checkbox"/> Bladder | <input type="checkbox"/> Bones | <input type="checkbox"/> Brain | <input type="checkbox"/> Gallbladder |
| <input type="checkbox"/> GE-tract | <input type="checkbox"/> Glands | <input type="checkbox"/> Heart | <input type="checkbox"/> Kidneys |
| <input type="checkbox"/> Liver | <input type="checkbox"/> Lungs | <input type="checkbox"/> Muscle | <input type="checkbox"/> Pancreas |
| <input type="checkbox"/> Reproductive organs | <input type="checkbox"/> Spleen | <input type="checkbox"/> Thymus | <input type="checkbox"/> Other |

30. Original animal ethics committee application or number of application

Please upload the original animal ethics committee application for this study, provide a link to an online copy or provide the number of the application

31. Additional information

Please give any other information about the study that is not covered elsewhere in the form

32. Link to data

Please provide links to any related published articles, or data provided in any data repository (e.g. Dataverse, Open Science Framework, Figshare, Zenodo)

33. * Embargo

You may choose to embargo the details of this study for up to 1 year from the date of registration. Please indicate below whether you want the details embargoed

Yes, embargo the details of this study

No, I do not want the details of this study embargoed

34. * Statement of accuracy

I confirm that the information provided in this form is true, complete and accurate